TITLE 21 VACANCY ANNOUNCEMENT

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of Pharmaceutical Quality (OPQ)
Office of Program and Regulatory Operations (OPRO)
Division of Regulatory and Business Process Management III

Position: Supervisory Consumer Safety Officer (Division Director)

Series: AD - 696

Location(s): White Oak, Silver Spring, MD

Travel Requirements: Up to 25%

Application Period: May 5, 2020 – May 11, 2020

Salary: Starting at $162,339

Conditions of Employment: United States Citizenship is required.

Relocation Expenses Reimbursement: Relocation expenses will not be paid.

Special Notes: This position is being filled under an excepted hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of the authority.

Additional information on 21st Century Cures Act can be found here.

Introduction:

The Food and Drug Administration (FDA or Agency) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The Center for Drug Evaluation and Research is responsible for regulating prescription drugs, including new drugs, generic drugs, biological products and biosimilars as well as over-the-counter drugs. CDER's drug regulatory responsibilities include premarket review of new drugs

and generic drugs; maintenance of the OTC drug monograph system; monitoring of all marketed drug safety and promotion activities; review, monitoring, and enforcement of drug quality during the entire drug life cycle; and ensuring drug products in the market comply with the law.

The Office of Program and Regulatory Operations (OPRO) is accountable for leading and coordinating regulatory review processes, facilitating a quality management system, and maintaining a learning and professional development program in collaboration with review offices within the Office of Pharmaceutical Quality (OPQ). Specifically, OPRO is responsible for managing all processes associated with drug product quality review and facility inspections.

Position Summary:

As the Division Director, the incumbent oversees and directs all operations, functions, and activities of the division as carried out by two subordinates branch chiefs and highly trained professional and technical staff. The division designs, develops, and implements internal processes to support drug quality assessment, in collaboration with the other Office of Pharmaceutical Quality (OPQ) offices and the Office of Regulatory Affairs (ORA). The scope of responsibility encompasses the management of post-market activities including the drug quality reviews of supplemental New Drug Applications (NDAs) and supplemental Abbreviated New Drug Applications (ANDAs).

Supervisory responsibilities: Manages the functional discipline, providing leadership and management oversight to subordinate staff. Supervises and evaluates staff of branch chiefs who serve as experts in their field. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff performing the work and functions of the organizational unit. Obtains and identifies strategic objectives for the organization.

Duties/Responsibilities:

- Provides leadership, review and oversight for Division programs for the planning, focusing, and coordinating of Branch activities. Direct project management staff in facilitating the postmarketing assessment process for drug quality.
- Directs specific drug regulatory and quality initiatives pertaining to postmarketing activities including appropriate project monitoring and progress tracking to ensure conformance with internal processes and procedures. The responsibility requires an ability to design, evaluate and implement pharmaceutical quality, surveillance, and inspection programs.
- Leads and oversees initiatives regarding regulatory guidance and project management and provides advice on the review process and procedures. Assumes primary responsibility for ensuring that regulations, policies, regulatory workflow developed are

consistent with statutory requirements and division policy. Ensures scientific reviews and project documents are thoroughly and accurately completed.
- Provides leadership on processes related to other post-marketing assessments including Field Alert Reports (FARs), surveillance inspections, and drug shortage activities.

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation, sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor.

- Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits.

Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when:

- An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job.
- An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace.
- An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events.

You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis.

Learn more about disability employment and reasonable accommodations or how to contact an agency.

Professional Experience/Desirable Qualifications:

To meet specialized experience requirements, the applicant's work experience must have demonstrated the knowledge, skills, abilities, and competencies necessary to perform at the level of the position. Qualifying experience involves enforcing laws and regulations to protect consumers from drugs that are defective, dangerous, impure, unwholesome, ineffective, or improperly or deceptively labeled or packaged.

- Demonstrated supervisory experience in diverse organizations
- Knowledge of the regulatory assessment process and project management skills
- Demonstrated ability to develop networks and build alliances; collaborates across boundaries to build strategic relationships and achieve common goals
- Ability to identify the internal and external politics that impact the work of the organization; perceives organizational and political reality and acts accordingly
- Demonstrated ability to identify and analyze problems; weighs relevance and accuracy of information; generates and evaluates alternative solutions; makes recommendations
- Successful experience in organizational change management
- Expert ability to communicate, verbally and in writing, and work with staff at all levels of the organization and varying levels of domain expertise; excellent listening skills and a commitment to communicate in a timely manner
- Ability to work independently and as a contributing and collaborative team member
- Ability to organize time effectively, determine priorities, and move work forward

Key requirements will include:

Desirable Education:

Degree: A bachelor's or graduate/higher level degree in quality assurance or a related degree that included at least 30 semester hours in one or a combination of the following: consumer laws, biological sciences, food science, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science , engineering, epidemiology, veterinary medical science, legal investigations, law enforcement, or related scientific fields that provided knowledge directly related to consumer safety officer work. The 30 semester hours may include up to 8 hours in statistics, or course work that included the principles, theory, or practical application of computers or computer programming. OR Combination of education and experience-courses consisting of at least 30 semester hours in the fields of study shown above, plus appropriate experience or additional education. Consumer Safety Officer, Series 0696

Conditions of Employment:

Security Clearance:

If not previously completed, a background security investigation will be required for all

appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Ethics Requirements:

This position is subject to strict prohibited financial interest regulations which could restrict the type of financial interest (stock holdings) for the employee, the spouse, and minor children of the employee. Selectee for this position will be required to file a Confidential Disclosure Report (OGE 450 or 278) and may require the selectee to obtain clearance from the FDA Division of Ethics and Integrity before a final offer can be made. For additional information on the prohibited financial interests, please visit the FDA Ethics and Integrity Office website at https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

How to Apply: All qualified candidates should submit a curriculum vitae and cover letter describing why you are uniquely qualified for this position, including how you possess the desired experience and qualifications identified above, electronically by May 11, 2020 to: OPQ_Cures_Recruitment@fda.hhs.gov. For questions please contact Dominique Mitchell, Supervisory Administrative Officer, via email at Dominique.Mitchell@fda.hhs.gov. Please reference Job Code: Division Director, DRBPMIII.

The Department of Health and Human Services is an equal opportunity employer with a smoke free environment.

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